

REMARKS

This application is amended in a manner believed to place it condition for allowance.

Claim 59 is amended to further define the stabilizer, and the type of tissue suitable for the claimed invention's use.

Claims 60-84 are amended as to form to be definite.

Claim 85 is new. Support may be found, for example, at specification page 9, line 4, page 19, lines 14-16, and Figures 11 and 12, which show suction nozzles 62 and 72 arranged on the outside surface of a ring and suction rods 63, 73, which are connected to the nozzles through the internal body of the ring.

Claims 59-85 remain in this application.

The Official Action rejects claims 59-84 under 35 USC §103(a) as being unpatentable over ABRAMS et al. US 6,740,098 ("ABRAMS") in view of KUBOTA et al. US 5,154,723 ("KUBOTA"). This rejection is respectfully traversed.

The claimed invention

The claimed invention concerns an assembly comprising an instrument to be positioned in or around a passage surrounded by body tissue, in particular vascular tissue, and a stabilizer for stabilizing said body tissue surrounding the passage with respect to the instrument.

The tissue surrounding such passages is inherently soft tissue and will usually be movable with respect to the surrounding tissue. For example, vascular tissue will frequently

move due to the blood pumped around through the body. This makes operations onto such soft, movable body tissue difficult, especially when high accuracy is required.

By providing, according to the invention, an assembly comprising a) a stabiliser having a loop of suction nozzles which can suck tightly against tissue close to and around said passage, and b) an instrument with a head section, which assembly has stops which in contact unambiguously define the position of the head section of the instrument with respect to the loop of suction nozzles on the stabilizer, one achieves an assembly which can be used with high accuracy once the surrounding body tissue is stabilized with respect to the instrument. Stabilizing the surrounding soft, movable body tissue with respect to the instrument by means of the loop of suction nozzles means that movement of the body tissue will cause an identical movement of the instrument so that the position of the instrument with respect to the site of operation is left unchanged.

ABRAMS

ABRAMS fails to disclose or suggest the claimed invention. Specifically, ABRAMS fails to disclose a stabilizer for stabilizing the surrounding body tissue with respect to the instrument, and ABRAMS fails to disclose stops for determining the relative positions of the stabilizer and instrument with respect to each other unambiguously.

ABRAMS discloses a device for the *purpose (a)* achieving a desired configuration of two hollow anatomical structure parts with respect to each other with the use of a pressure differential device and the *purpose (b)* subsequently deploying a support staple to stabilize the achieved configuration. See, e.g., column 1, lines 22-28 and column 2, lines 26-34.

The ABRAMS device is especially used for treatment of incontinence by reducing the diameter of the urethra near the bladder and/or shortening the length of the urethra near the bladder. Thus, a configuring system comprising the pressure differential device is used for purpose (a), achieving the desired configuration, and a stabilizing element, the staple, is deployed/inserted for purpose (b), stabilizing the achieved configuration.

The Official Action incorrectly combines two different embodiments of ABRAMS. Figures 2-13 show essentially one embodiment, but Figures 22-28 show another embodiment, see column 5, line 37 'an alternative embodiment' and column 11, lines 32-37 'figures 22-28 show cross sections of a preferred embodiment'. However, both embodiments operate differently and cannot be combined.

The Figure 2-13 embodiment of ABRAMS

The configuring system according to Figures 2-13 comprises:

- A hollow vacuum tube 80, having through its wall a

plurality of suction apertures 90 (column 7, lines 62-64). A vacuum port 100 is provided to draw a vacuum through tube 80 and suction apertures 90 (column 8, lines 1-2).

- A balloon 150 which is connected to a pressure port 150 for inflating the balloon 150 (column 8, lines 28-30).

The stabilizing element of this embodiment comprises a staple 60 arranged on a staple holder 20. This staple holder 20 extends through the vacuum tube 80 and its distal head 40 carrying the staple 60 lies proximally outside the vacuum tube 80. This distal head of the staple holder also carries the balloon 150.

For use, one inserts the device 10 through the urethra 160 up to the head 40 of the staple holder 20 (with staple 60 and balloon 150) has passed through the bladder neck 175 and thus lies inside the bladder 170, see column 8, lines 45-50. The vacuum tube 80 lies inside the urethra 160. Once inserted, the balloon is inflated to extend to a deployed condition (Figure 11) and to create a seal between the bladder 170 and the urethra 160. See column 8, lines 56-61. Subsequently, once the balloon is inflated, see column 8, lines 62-67, a vacuum is pulled through the vacuum port and the apertures 90 of the vacuum tube 80. This passage continues with "The created vacuum condition in urethra 160 pulls balloon 150 towards urethra 160 to affect the above described seal and pulls the sides of urethra 160 into a substantially tight relationship against vacuum support 80." As

described in column 9, lines 13-18, this creates, possibly with some other manipulation, the desired configuration of the urethra and bladder (purpose a). Subsequently, see column 9, lines 19-21, the staple is implanted to maintain this desired configuration of the neck region of the urethra (purpose b).

The manner of implantation of staple 60 is described in column 9 lines 29-41. The handle 35 (Figure 2) of staple holder 20 is pulled in proximal direction by the surgeon. This traction pulls the staple 60 into the tissue of neck 175 to hold the neck in the desired (normal) shape. Next staple 60 is released from the staple holder.

The Figure 22-28 embodiment of ABRAMS

This Figure 22-28 embodiment differs from the Figure 2-13 embodiment in the manner of achieving the stabilization by means of the staple. The staple element and its manner of releasing are quite different.

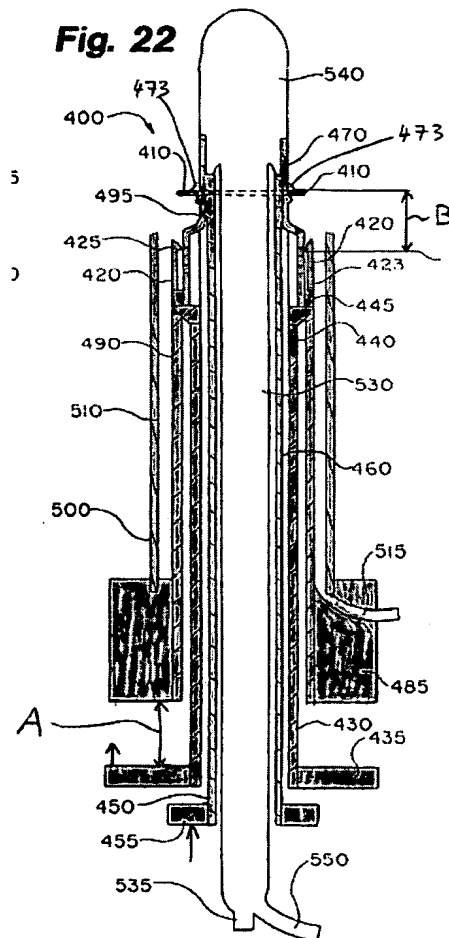
Referring to column 12 lines 15-25, the suction tube 500, the balloon 540 and their use are 'substantially as described earlier'.

The staple element consists of two parts, a staple ring 410 and a staple 420. The needles 423 of the staple are directed in proximal direction and have barbs 425 for a snap engagement with the staple ring 410, see column 11, lines 38-45.

This staple element requires a more complicated mechanism to use it. Not only the ring 410 and staple are to be

released from the device 400, but first the staple ring 410 and staple 420 are to be brought together to obtain the mutual snap engagement. A staple insertion/actuator mechanism 430 as well as a staple ring retainer/release mechanism 450 are provided for this purpose. See column 11, line 51 and further.

Figure 22 of ABRAMS, discussed in column 11, line 51 to column 12, line 8, is shown below with shading to indicate the key features:



The insertion/actuator mechanisms 430 and retainer/release mechanism for the staple function as follows

(after inflating the balloon and placing the vacuum tube 510 under vacuum):

- Parts 470/473/485/490/495/500/510/515 are rigidly fixed to each other

- Parts 430/435/440/445 are rigidly fixed together;

- Parts 450/455/460 are rigidly fixed together;

- Parts 420/425/435 are rigidly fixed together;

- Part 410 is a staple ring, not rigidly fixed to part 470;

- The device support 480 carries a) the vacuum tube 500 with suction apertures 510 (see also figure 27), and b) tube 490 (see column 12 line 11);

- The insertion/actuator mechanism 430 has a handle 435 and leg members 440 provided with a pedestal 445 (column 11, lines 51-53);

- The retainer/release mechanism 450 has a handle 455 and outwardly biased retaining legs 460 provided with staple ring engaging tips 470 (column 11, lines 61-63).

- To operate the surgeon moves handle 435 further into the urethra (i.e., direction indicated by the arrow on the left portion of 435 indicated in the figure), which causes the leg member 440 and pedestal 445 to push staple 420 (upwards) along the inner supporting tube 495 towards the staple ring 410. The barbs 425 on the needles of the staple 420 pierce in the

tissue and snap behind staple ring 410 for secure engagement.
See, column 11 lines 54-60.

- Subsequently, see column 12, lines 1-5, the surgeon urges the release mechanism 450 further into the urethra (i.e., direction indicated by the arrow near item 455). This causes ramped portions 473 of the tips 470 to ride within tracks in the outer tube, which in turn urges retaining legs 460 inwardly to clear the staple ring 410.

Differences between the claimed invention and ABRAMS

The suction tube 510 of ABRAMS has suction apertures 510 allowing fixation of the urethra onto this suction tube 510. Thus, the suction tube 510 of ABRAMS acts as a 'stabilizer', which includes parts 470/473/485/490/495/500/510/515. Accordingly, the insertion/actuator mechanism 430, i.e., formed by parts 430/435/440/445, and retainer/release mechanism 450, i.e., formed by parts 450/455/460, are, collectively, the 'instrument'. Both mechanisms are moveable with respect to the suction tube 510.

According to the claimed invention, however, the stabilizer is provided with an instrument stop and the instrument is provided with a stabilizer stop, which when contacting each other unambiguously define the position of the head section with respect to the loop of suction nozzles. ABRAMS fails to disclose or suggest such stops.

In the Office Action, it is alleged that ref. 435, ref. 455 and ref. 485 would act as stops. However, this is incorrect because:

- alleged stops 435 and 455 both belong to and are provided on the instrument part of the device, and would consequently be so called 'applicator stops';

- alleged stop 485 is provided on the stabilizer part of the device, and would consequently be the so called 'stabilizer stop';

- taking into account that 'applicator stop' 435 lies in between the 'stabilizer stop' 485 and the 'applicator stop' 455, it is clear that the stop 455 and stop 485 can not contact each other to define unambiguously the position of the suction tube 500 and instrument with respect to each other;

- taking into account that the distance of movement B required to bring the red staple 420 into snap engagement with the red staple ring 410 is smaller than the distance A between stop 485 and stop 435 ($A=13.5$ mm and $B=16$ mm), it is clear that the stops 435 and 485 are unable to contact each other as always a gap (of 2.5 mm) will remain.

Further, it is to be noted that a) ABRAMS does not explicitly say that the movement of the 'stabilizer' of the device, i.e., parts 470/473/485/490/495/500/510/515, with respect to the 'instrument', i.e., comprising parts 430/435/440/445 and parts 450/455/460, is limited with respect to

each other in a stop position in order to unambiguously define their mutual positions, and even more important that b) the teaching of ABRAMS is that the 'stabilizer' part of the device, on the one hand, and the 'instrument' part of the device, on the other hand, must have freedom of movement with respect to each other in two opposing directions so that their positions will never be unambiguously defined with respect to each other.

In this respect it will be clear that as from the position shown in Figure 22, part 435, 430 must be able to move upward with respect to part 485, 500, 490 as otherwise the staple 420 can not be moved towards the staple ring 410 while at the same time part 500 and staple ring 410 are fixed with respect to the urethra.

But ABRAMS teaches also that the 'instrument' part 430, 460 must be able to move downwards with respect to the 'instrument' part 500. This follows from column 8 lines 64-65 (which according to column 12 lines 17-18 also applies to the figure 22-28 embodiment), where it is said that the vacuum created in the urethra by means of the suction tube 500 pulls the balloon towards the urethra. This is only possible when the 'instrument' part carrying the balloon and the 'stabilizing' part carrying the suction tube are movable with respect to each other in the sense that the 'instrument' part moves downwards with respect to the 'stabilizer' part.

Thus, ABRAMS does not disclose steps defining the mutual position of the 'stabilizer' part with respect to the 'instrument' part unambiguously.

Indeed, ABRAMS does not disclose a stabilizer according to the claimed invention, as ABRAMS does not disclose a stabilizer for stabilizing the tissue with respect to the instrument. The ABRAMS instrument part is freely moveable with respect to the ABRAMS stabilizer part. The alleged 'stabilizer' part of ABRAMS only positions two flexible tissue parts with respect to each other.

The KUBATO publication

KUBATO relates to cerebral surgery. KUBATO discloses a stereotaxic instrument 1 which is fixed to the head of the patient (column 5 lines 6-9). The treating instrument for treating the affected part (by removal) of the patient is elongate and fixed to the stereotaxic instrument. In order to be able to move this instrument axially in the elongate direction it is arranged on a sliding body. This sliding body is inscribed with a scale 90b and reference line 86 a so that a certain amount of longitudinal movement can be ascertained (column 8 lines 40-46).

The stereotaxic instrument is rigidly fixed by means of screws 13 to the skull of the patient (column 5, lines 25-27). This stereotaxic instrument is thus fixed relative to a hard and solid part of body of the patient and not with respect to the

soft tissue part itself, which is to be treated. This soft tissue part, in this case a part of the brain or other tissue inside the skull, is, as one knows, not fixed with respect to the skull and movable with respect to the skull. Consequently this soft tissue part will be moveable with respect to the treating instrument.

Thus, KUBATO does fails to teach or suggest fixating soft tissue with respect to the treatment instrument or with respect to a stabilizer having a predetermined positional relationship with respect to the treatment instrument.

The combination of ABRAMS and KUBOTA

ABRAMS relates to achieving a desired configuration of two hollow anatomical soft tissue parts and fixing those parts permanently into this configuration.

KUBOTA relates to cerebral surgery with immobilizing the head temporarily in order to remove soft tissue.

The combination of the publications does not result in the claimed invention. At best, the combination would result in fixing the instrument with respect to bone material of the patient but not in fixing the instrument with respect to the soft tissue by stabilizing the position of the soft tissue with respect to the instrument for treating the soft tissue.

Thus, independent claim 59 is not rendered obvious by the proposed combination. Neither publication discloses stabilizing soft, movable body tissue surrounding a passage with respect to an instrument inside or around the passage in a manner

that the relative positions of instrument and stabilizer are unambiguously determinable.

As to new claim 85, it is essential for ABRAMS to create a vacuum condition in the urethra as such, thus not only between the urethra wall and the suction nozzles but also in the rest of the urethra. This follows from column 8 lines 64-65 (otherwise the balloon, which lies axially away from the suction tube, cannot be pulled towards the urethra as well as column 10 lines 22-23, which explicitly says that the interior chamber 210 (i.e., the cylindrical space inside the suction tube) is drawn vacuum. The suction nozzles of ABRAMS thus are apertures connecting the inner cylindrical space with the outside of the suction tube, i.e. they extend radially completely through the tubular wall.

However, for the claimed invention, e.g., new claim 85, the stabilizer is provided with a ring shaped suction body comprising said one or more suction nozzles running in the shape of said loop, wherein the loop extends in circumferential direction of the suction body, and wherein the suction means comprise a suction line opening into a suction passage formed in the interior of the suction body, which suction passage, in turn, is in communication with the suction nozzle.

The advantage of this feature is that the application of suction is much more controlled and dedicated to specifically the tissue to be stabilised. In case the internal cylindrical

space of the ring shaped ring would be placed under vacuum, like is the case in ABRAMS, this would result also in sucking in permanently blood or air from the surrounding, which would not only make the fixation of the tissue surrounding the passage ineffective but would also cause other undesired effect like attraction of other tissue in the direction of the site of operation.

Additionally, with respect to claim 64, in particular, this feature is also neither disclosed nor suggested by either publication. The guide is provided at the proximal end of the working duct, and (claim 63) the suction nozzles are provided at the distal end of the working duct, means that the guide carrying the stops (claim 61) is provided at a distance from the site of operation. This allows a better view on both the guide and the site of operation.

Therefore, for the reasons discussed above, the proposed combination cannot render obvious claims 59, 63, and 85, as well as 60-62 and 64-84, and withdrawal of the rejection is respectfully requested.

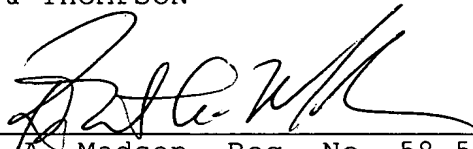
In view of the amendment to the claims and the forgoing remarks, applicant believes that the present application is in condition for allowance at the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Please charge the fee of \$25 for the extra claim of any type added herewith, to our credit card as set forth on the attached Credit Card Payment Form.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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